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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,950	11/03/2003	Darren Hodson	3764-150	5024

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ARLINGTON, VA 22203

EXAMINER
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DAWSON, GLENN K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/698,950

Applicant(s)

HODSON ET AL.

Examiner

Glenn K. Dawson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-48 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 21-48 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☒ Certified copies of the priority documents have been received in Application No. PCT/SE98/02038.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### ***Claim Objections***

Claims 31 and 33 are objected to because of the following informalities:

In claim 31, the use of "in particular" is objected to as it is unclear if the dose counter is being positively recited.

In claim 33, the phrase "the breath the compliance monitor" requires re-wording.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-23,25-37,39-41 and 43-48 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ritson, et al.-5520166 in view of Goldsmith, et al.-5334019.

Ritson discloses an inhaler having a cassette consisting of a tubular body receiving a canister and a mouthpiece. The mouthpiece and the tubular member are connected by tabs or ears and apertures. Depending on how the tube and mouthpiece are held, the bottom portions could be any end or side of the device. Therefore, the apertures 28 could be placed at a top and bottom position, and the end 48 of the tube could be placed at the bottom. It is also disclosed that it is desirable to make the removal of the cassette components such that the cassette components cannot be reused. The examiner maintains that upon sufficient force being applied to the mouthpiece and the tube that portions of the mouthpiece would deform or break such that it could not be re-used. If this is not found to be persuasive, the examiner turns to

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Goldsmith, which teaches of providing a disposable mouth nozzle 24 with a breakaway tab to prevent reattachment and reuse of the nozzle. See col. 5 lines 57-68. It would have been obvious to have provided the mouthpiece of Ritson with a breakaway tab or some other type or projection for receipt by the tubular member of Ritson, as this would provide a known means to prevent re-use of the mouthpiece to prevent possible disease transmission.

Claims 24,38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritson-'166 in view of Goldsmith, et al.-'019.

Ritson discloses the invention as claimed with the exception of the lateral opening on the tubular member. It would have been obvious to have provided the openings on the tubular member instead of on the mouthpiece as merely being an obvious reversal of known parts.

Making the parts of different colors would have been obvious as different colors of the tube could identify different medications.

### ***Response to Arguments***

Applicant's arguments filed 03-15-2006 have been fully considered but they are not persuasive.

The examiner contends that possibly the tabs on the tube would break; however, it is also possible that the apertures 28 could be broken out, or the nozzle block could be snapped off by torque produced by the valve stem. Either of these would break the mouthpiece such that it could not be re-used. However, if that is not persuasive,

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Goldsmith clearly teaches that it was known to provide a breakable tab on a nozzle (analogous to the mouthpiece) so that it cannot be re-attached and reused.

### ***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract still contains legal phraseology, such as ... "comprising".

Correction is required.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Glenn K Dawson  
Primary Examiner  
Art Unit 3731

Gkd  
19 May 2006